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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,888	09/25/2003	JoAnne J. Fillatti	16518.133	4299

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ARNOLD & PORTER LLP
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WASHINGTON, DC 20004-1206

EXAMINER

PAGE, BRENT T

ART UNIT	PAPER NUMBER
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1638

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/25/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/669,888	Applicant(s) FILLATTI ET AL.	
	Examiner Brent Page	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31,33-38 and 75-98 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31,33-38 and 75-98 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Arguments

Claim Objections

Claims 95-98 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claims, or amend the claims to place the claims in proper dependent form, or rewrite the claims in independent form. New Matter should be avoided.

Claims 95-98 recite "wherein said FAD2 intron is a fragment of a FAD2 intron". An "intron" is generally known in the art to be a full-length intron unless specified otherwise in the specification or parent claim. There is no further guidance to indicate that the recitation of "a FAD2 intron" would also encompass fragments of the intron, and therefore the New Claims actually broaden the subject matter of the parent claims 75-76 and 84-85 and therefore are improperly dependent.

Claim Rejections - 35 USC § 112

Claims 31, 33-38, and 75-94 remain rejected and New Claims 95-98 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the suppression of soybean FAD2 and FATB with expression of soybean FAD2 and FATB DNA sequences and the increase of expression of soybean delta-9 desaturase with the expression of exogenous soybean delta-9 desaturase, does not reasonably provide enablement for the above described expression alterations with any DNA sequences as broadly claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The claims are rejected for the reasons of record in the previous office action pages 2-5.

Applicant's arguments filed 11/03/2006 have been fully considered but they are not persuasive.

Applicants urge that the Examiner has not met the evidentiary burden to impose an enablement rejection and state specifically "A specification that discloses how to make and use a claimed invention **in terms which correspond in scope** to those used in describing and defining the subject matter sought to be patented 'must be taken as in compliance with the enabling requirement of the first paragraph of § 112 unless there is reason to doubt the objective truth of the statements contained therein'" (emphasis added by Examiner).

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This is not persuasive because the specification defines specific DNA sequences for the suppression of soybean FAD2 and FATB and specific DNA sequences for the increased expression of soybean delta-9 desaturase, which **does not correspond to the scope** of the claims which do not specify or limit the types of DNA sequences that are to be used for this function either by species source **or** by gene, and particularly does not limit them by SEQ ID NO.

Applicants also urge that the cited reference by the Examiner in the previous office action to demonstrate unpredictability is beyond the scope of the present invention and that the instant claims are not directed to efficiency of fatty acid production.

This is not persuasive because the cited reference demonstrates that the transgene source has an unpredictable effect on fatty acid synthesis. While Applicants' claims may not be directed to efficiency per se, they are directed the suppression of gene products involved in fatty acid synthesis, and therefore the unpredictable nature of transgene source demonstrated by Singh et al is evidence that one of skill in the art could not use any gene from any gene source for the suppression of FAD2 or FATB genes in soybean.

Applicants further urge that the considerable direction, guidance, and working examples provided by Applicants make any conclusion that undue experimentation would be required inconsistent with the provided guidance, and that the Office has provided inapplicable generalizations regarding unpredictability in the art.

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This is not persuasive because Applicant's claims are not commensurate in scope with the guidance provided by the specification. The broadness of the claims in which ANY DNA sequence from ANY source may be used to suppress the expression of soybean FAD2 and FATB, would read on literally any art that discloses unpredictability of a transgene. However, it is drawn to Applicant's attention that the art used is directed specifically to fatty acid synthesis genes, and is therefore applicable to the claims.

Claims 31, 33-38, and 75-94 remain rejected and New Claims 95-98 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant's arguments filed 11/03/2006 have been fully considered but they are not persuasive.

Applicants urge that the specification provides guidance for the suppression of more than soybean sequences. The amendment of the claims by Applicants render this argument moot.

The claims above remain rejected for the reasons of record on pages 5-7 of the previous office action. In particular Applicants are reminded that the claims are drawn to the suppression of FAD2 and FATB with ANY DNA sequence from ANY source, as well as the increase of expression of a delta-9 desaturase with the expression of ANY DNA sequence from ANY source.

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New Claims 95-98 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

New Claims 95-98 recite "a fragment of a FAD2 intron". There is no support in the specification for this phrase and therefore these claims are directed to New Matter. Applicant is required to delete New Matter.

Claim Rejections - 35 USC § 103

Claims 31, 33-38, 75, 78-84, and 87-94 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Buhr et al in view of Thompson et al, for the reasons mentioned on pages 7-10 of the previous office action.

Applicant's arguments filed 11/03/2006 have been fully considered but they are not persuasive.

Applicants urge that even when combined, the teachings of Buhr et al and Thompson et al do not teach or suggest the claimed invention and that there is no motivation in either reference to combine the suppression of FAD2-1 and FATB with increasing the expression of the endogenous delta-9 desaturase gene or any reasonable expectation of success. Applicants further urge that the office is using the Applicant's specification as a hindsight guide to combine the references.

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This is not persuasive because the suppression of FAD2-1 and FATB in transgenic soybean plants was disclosed in the prior art, and the increased expression of endogenous delta-9 desaturase was disclosed in the prior art. The state of the art at the time of the invention reflects that such constructs were already disclosed, and both prior art references taught the alteration of oil content associated with the constructs. The statement by Thompson et al cited in the previous office action on page 9 regarding desired oil contents and the suggestion to modify the plant to achieve such alternatives would motivate one of ordinary skill in the art to combine oil content altering constructs to do so as previously asserted in the office action.

Furthermore, Applicant's arguments of unexpected results are drawn to the use of particular FAD2 and FATB introns or UTR sequences from a particular plant species. In contrast, the claims are broadly drawn to the use of any DNA sequences from any crop species, any gene, any region of the gene, and of any sequence, which DNA sequences somehow suppress the expression of soybean FAD2 and FATB genes.

See *In re Lindner*, 173 USPQ 356 (CCPA 1972) and *In re Grasselli*, 218 USPQ 769 (Fed. Cir. 1983) which teach that the evidence of nonobviousness should be commensurate with the scope of the claims.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only

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knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Applicants further urge that claims 78-83 and 87-92 do not recite multiple design choices because claims 75-76, 84-85 and 95-98 recite the use of "a FAD2 intron or fragment thereof".

This is not persuasive because the basis of the argument is the term "or fragment thereof" which has been deemed New Matter in claims 95-98 and is not recited at all in claims 75-76 and 84-85.

Double Patenting

Claims 31, and 33-38 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 31, and 33-38 of copending Application No. 10508401.

The Examiner acknowledges the statement that Applicants would be willing to submit a Terminal Disclaimer in the present case upon indication of allowable subject matter.

Claims 76-77 and 85-86 are free of the prior art given the failure of the prior art to teach or reasonably suggest a DNA construct comprising a FATB UTR.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brent Page whose telephone number is (514)-272-5914. The examiner can normally be reached on Monday-Friday 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571)-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brent T Page

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180-1638

